
From: Cynthia Sherman [/O=REGENERON/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CYNTHIA.SHERMAN]
Sent: Tuesday, August 09, 2011 5:53:54 PM
To: Robert Terifay
CC: Robert Davis
Subject: RE: Copay Foundation
Attachments: Len Presentation.pptx

Hi Bob,

Please see attached presentation with updates:

- Slide 28 has updates for the RPAP (based on last week's conversation)
- Slide 35 has updates to the Gov't copay foundation

Please let me know if you require any other changes.

Cynthia

From: Robert Terifay
Sent: Tuesday, August 09, 2011 1:35 PM
To: Cynthia Sherman
Cc: Robert Davis
Subject: RE: Copay Foundation

Put it in the Len slides please.

From: Cynthia Sherman
Sent: Tuesday, August 09, 2011 8:58 AM
To: Robert Terifay
Cc: Stephen Dressel; Robert Davis
Subject: Copay Foundation

Bob,

Steve and I had the chance to discuss the funding levels for the two Copay Foundations we are looking to support, PANF and CDF. We ran calculations based on the estimated percentage of Medicare patients without secondary coverage. We believe that the following payment levels would suffice:

- Payments to CDF equating to \$125,000 per quarter
- Payment to PANF equating to \$75,000 per quarter

Steve and I plan to hold calls with both foundations at the end of each quarter to determine if the funding amount is on target for our patient population. Even though we cannot get a breakdown of our spend by EYLEA users, they can let us know if we are supporting the bulk of our patients. We are proposing the following funding timelines: September 15, 2011, December 15, 2011....

Please let us know if you have additional questions or concerns. The donation letters have been vetted by legal so we can turn this around immediately upon approval. Thanks!

Cynthia Sherman

Senior Director, Reimbursement

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Trade and Distribution

Robert Davis

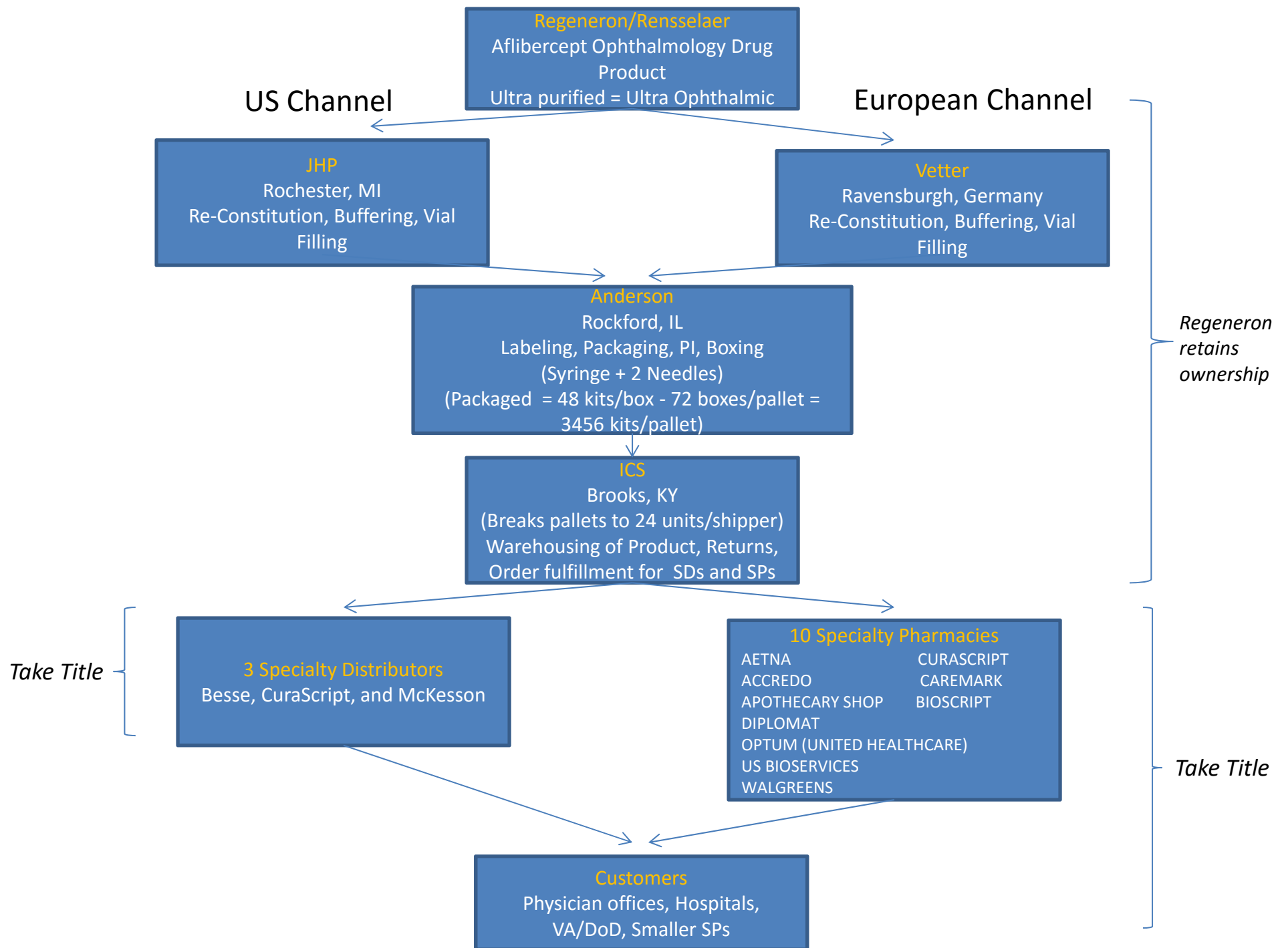
August 5, 2011

REGENERON

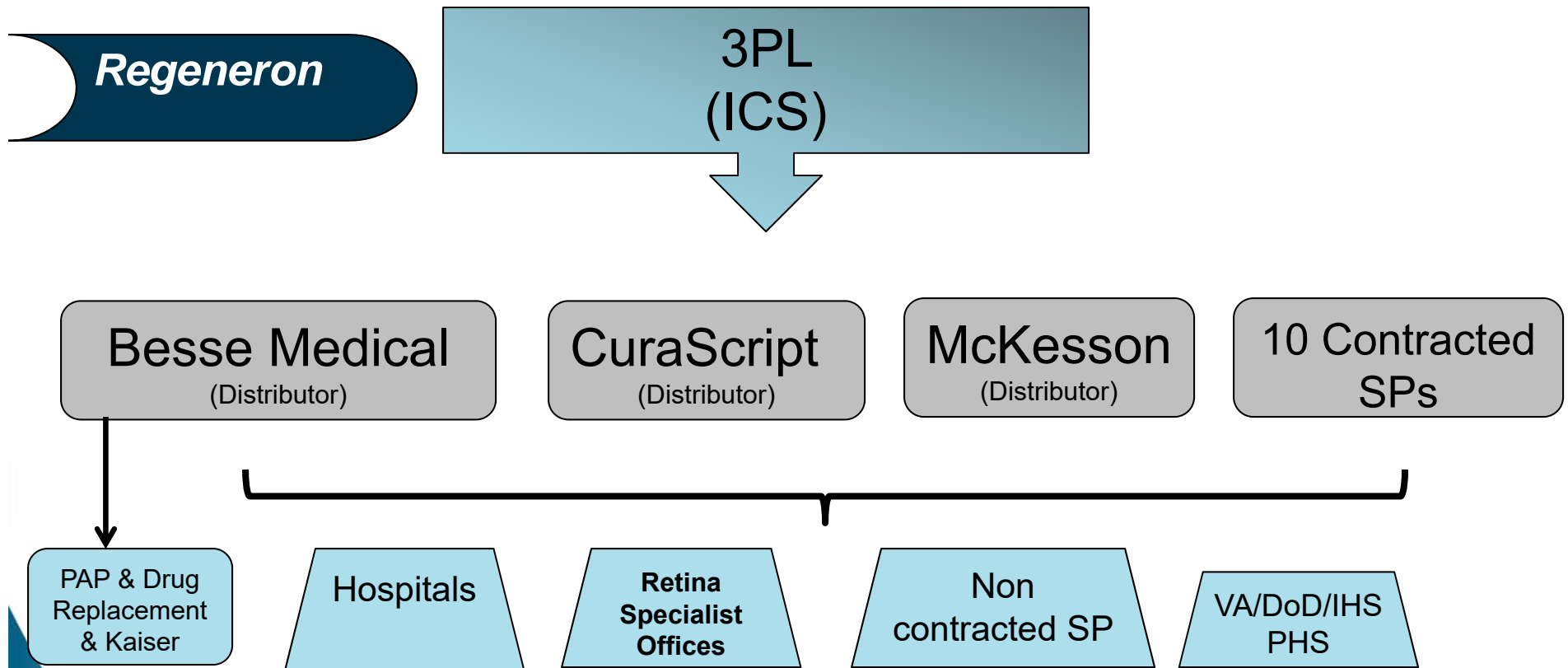


Supply Chain





EYLEA Supply Chain Model



Packaging

Anderson:

- EYLEA packaged in 48 kits/box – 72 boxes/pallet (3456 kits/pallet)
 - 40 mg/mL solution single-use, glass vial (2mg of product)
 - Pallets sent to ICS

ICS:

- Breaks pallets to 24 kits/shipper (minimum order size)
- Only sells 24 pack to 3 distributors and contracted SP's
- Styrofoam Shipper

Distributors Services Provided for 3%

- Online ordering and account management offering for provider customers
- Full line of products in category
- Qualified work force for cold chain, expensive products
- Management team experience in national full-line wholesale distribution
- Wholesale licenses in all 50 states
- Adequate legal and regulatory resources with wholesale experience
- Adequate levels of insurance
- Pedigree reporting where and when required, including FL
- Warehouse audit required
- Strong financial condition – audited financial statements if non-public company
- Excellent established wholesale relationships with current customer types: specialty pharmacies, physician clinics, and hospitals
 - Distribution agreements for all approved products in this class
- Processes in place for account validation and monitoring
- This Fee also includes daily and weekly sales and inventory data feed to Regeneron
- The Fee for above Services = 3% of WAC Price per vial

Proposed Distribution Marketing Plan (inc 3%)

- Rotating Ad on Dist home page with link to product specific landing page, announcing the availability of EYLEA for the first 6 months of launch
- Initial fax and email broadcast to qualified potential buyers announcing the availability of EYLEA
- Include “Now Available” shipment insert in every customers EYLEA order for 6 months post launch
- Outbound call campaign to qualified potential buyers on day 1 announcing availability and ordering process of EYLEA
 - Follow up calls conducted one month later to potential buyers as additional reminder
- Inbound call campaign starting day 1 through 6 months post launch



Distributor Services Fee

- Bona Fide Fair Market Value Assessment was done by Compliance Implementation Services, LLC. (Regeneron Federal Reporting Vendor)
- Bona Fide Fair Market Value Assessment also reviewed and approved by Internal and External Legal Counsel
- This FMV fee is excluded from all ASP and Government pricing calculations
- No Prompt Pay Discounts Provided
- Title Model – All Financial Risk assumed by Distributors
- Industry average FMV Fee is 3 – 5%
- Currently Vertex is paying Besse 3.5%+ for same program 6/11

Credit Cards

- All 3 Distributors accept major Credit cards
- Regeneron just pays pass thru Fees (2.5%)
- Distributors assume all credit and collection risks
- Allow Doctors choice to buy thru Besse, Curascript and McKesson Specialty and use Major Credit Cards with Extending payment terms.
- Lucentis is only available Direct with Credit cards
- Distributors do not allow Credit card payment for Lucentis

Extended Payment Terms

- ❑ Recommend 150 day Payment Terms (120 +30) for Eylea to Physicians and 120 days to Specialty Pharmacies thru 12/31/2012

Rationale:

- ❑ With temporary J-Code until 1/1/2013 reimbursement to Physicians may take up to 4 months.
- ❑ Lucentis is currently offering 100 Days dating
- ❑ Physicians stated in the field and at Ad boards that 90 days is a non- starter due to delayed payment from Government

Specialty Pharmacies (SP)

- 10 contracted SP's cover estimated 90% of commercial lives

- Accredo
- BioScrip
- Apothecary Shop
- Caremark
- Walgreen's (Medmark /OptionCare)
- Curascript
- US Bioservices
- Diplomat
- Atena
- Optum Health (UHC)

— Additionally, Axiom SP May added to cover Puerto Rico

- Terms:

- Service fees for bona fide distribution services rendered
- ICS direct ship to 10 contracted SP's

- Dating:

- Proposed – 120 days



Specialty Pharmacy Service Fee = 1.5%

- Bona Fide Fair Market Value Assessment was done by Compliance Implementation Services, LLC. (Regeneron Federal Reporting Vendor)
- Bona Fide Fair Market Value Assessment also reviewed and approved by Internal and External Legal Counsel
- This FMV fee is excluded from all ASP and Government pricing calculations
- This 1.5% Service fee is for all services performed by Specialty Pharmacy Provider to include all data feeds from payers and providers to Regeneron as allowed by Law
- The industry average for Specialty Pharmacy fees is between 1 -3%



EYLEA™ Patient Assistance Program (PAP)

Cynthia Sherman
Sr. Director, Reimbursement

REGENERON

Reimbursement Objectives

- Set expectations and manage the experience
 - Ensure accounts have a positive experience with EYLEA™
 - Set office expectations for billing and reimbursement for EYLEA
 - Minimize reimbursement obstacles with EYLEA 4USM programs
 - Utilize all reimbursement resources to educate offices on process for successfully using a miscellaneous code to buy and bill



Hotline Services

- Prior Authorization (PA) Assistance
- Appeals Support for Denied Claims and PAs
- Benefits Investigation
- Claims Assistance (determination of claim status)
- Patient Assistance (uninsured)
- Alternative Funding Research
- Retroactive Patient Assistance (PAP and product replacement)
- Refer to Copay Assistance Foundations (Government and Manufacture Copay)

Overview – Scope of Program

■ Objective:

- The overall objective of the EYLEA 4USM Patient Assistance Program (PAP) is to support access to EYLEATM for uninsured patients. The PAP is designed to assist patients with no insurance coverage for EYLEA.

■ Program Goals:

- The primary goals of the EYLEA 4U PAP will be to:
 - Ensure appropriate access based on patient eligibility criteria.
 - Facilitate the scheduling of orders to distribute drug free of charge to patients enrolled in the program.
 - Identify and educate patients and providers on potential alternate sources of coverage
 - Provide access to patients during prior authorization and claim denial appeal support

■ Assistance:

- Customer Service Support
- PAP enrollment form processing
- Alternate coverage research
- Coordination of PAP order requests with Besse Medical



Eligibility

■ Current Eligibility Criteria:

- Patient must lack insurance coverage for EYLEA™
 - No coverage for or exclusion of EYLEA
 - Denied claim(s) or prior authorization for EYLEA
 - Pre-existing condition that cannot be waived
 - Catastrophic coverage limits
 - Met benefit cap or cost of treatment will place the patient over the benefit cap
- Must reside in the Territories or Commonwealths of the US including:
 - United States, Guam, US Virgin Islands, American Samoa, Puerto Rico, or the Northern Mariana Islands
- Must be administered EYLEA for an approved FDA indication
- Total yearly household income less than \$100,000



Enrollment

■ Enrollment:

- Fax a complete copy of the enrollment form to (888) 335-3264
- The patient will be required to provide a copy of the last Federal Tax Return (FTR)
 - The physician or patient can mail or fax the income documentation to EYLEA 4USM
- If the FTR is not available, the patient must provide a copy of his or her last two pay stubs/disability check/pension, etc..
- Once the completed enrollment form and income documentation is received, a program representative will process and make a determination of eligibility

EYLEA 4USM Patient Assistance Program

■ Current Program Design:

- Verification of benefits will be completed for all potential enrollees listing an active insurance plan
- Alternate coverage options will be researched for every PAP enrollment
 - Program representatives will educate and assist in the application process of the alternate source of coverage, and complete regularly scheduled follow up to check if coverage has been accessed
 - Patients will be discontinued from PAP once coverage for EYLEATM has been confirmed
- Patients will be approved for the PAP if the program criteria are met and a potential alternate source of coverage is not identified
- Eligibility period is 12 months, a renewal application will be sent 30 days prior to the eligibility end date

Assistance Provided

- Assistance is in the form of drug provided free of charge for the PAP patient
 - The first order will be automatically sent to Besse Medical for shipment upon program approval
 - Regular follow up will be made with the treating provider for documentation confirming another shipment is needed and that the patient's financial and insurance status has not changed
 - Orders will be sent from the program to Besse Medical once documentation from the treating provider has been received
 - Patients will be discontinued from the program if changes have occurred that make the patient ineligible under the program criteria

Additional Information

- Providers can initiate the patient assistance process via phone
- Incomplete patient assistance enrollment forms (e.g. missing income documentation or signatures) received by the program may be approved for one dose if the patient otherwise meets program criteria based on the information provided
 - Once a complete enrollment form is received, the patient can be approved for future doses in accordance with the program
- Correspondence for the EYLEA 4USM Patient Assistance Program is as follows:
 - Enrollment form: This can be faxed or mailed to the patient or provider and requires signatures from both patient and provider
 - Missing information letter: This can be faxed or mailed to the patient or provider and is used when the program has received an incomplete enrollment form
 - The missing information letter is used in conjunction with follow up calls
 - Determination letter: Patient and provider will receive notification via fax or mail stating if the patient is eligible for assistance through the program
 - EYLEA 4U Patient Assistance Program Address is as follows:
 - EYLEA 4U Reimbursement Support Program
PO Box 220578
Charlotte, NC 28222-0578





EYLEA™ Temporary Patient Assistance Program (T-PAP)

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EYLEA 4USM Temporary Patient Assistance Program- Pending Alternate Coverage

■ Current Program Design:

- Patients will be approved for temporary assistance if the program criteria is met and a potential alternate source of coverage is identified
 - Program representatives will educate and assist in the application process of the alternate source of coverage, and complete regularly scheduled follow up to check if coverage has been accessed
 - Patients will be discontinued from PAP if the alternate source of coverage has been accessed and coverage for EYLEATM has been confirmed
- Eligibility period is three months, a renewal application will be sent 30 days prior to eligibility end date

EYLEA 4USM Temporary Patient Assistance Program- Claim Denial

■ Current Program Design:

- Program representatives will assist sites in appealing a denied claim for EYLEATM, during which patients will be placed on temporary patient assistance to prevent delays in therapy
 - Patients will be discontinued from temporary PAP if the claim denial is overturned and coverage for EYLEA has been confirmed
 - Patients will be discontinued from temporary PAP and transitioned to unrestricted PAP if the claim denial is not overturned and the program criteria is met
- Program representatives will assist sites with information on filing an appeal should the initial claim be denied for EYLEA
 - Patients will be discontinued from temporary PAP if the appeal is approved and coverage for EYLEA has been confirmed
 - Patients will be discontinued from temporary PAP and transitioned to unrestricted PAP if the appeal is not approved and the program criteria is met
- Eligibility period is three months, a renewal application will be sent 30 days prior to eligibility end date



EYLEA 4USM Temporary Patient Assistance Program- Prior Authorization Assistance

■ Current Program Design:

- Verification of benefits and prior authorization requirements will be completed for all enrollments listing an active insurance plan
- Patients will be approved for temporary assistance if the plan indicates the prior authorization processing time will be greater than three business days
 - Patients will be discontinued from temporary PAP if the prior authorization has been approved and coverage for EYLEATM has been confirmed
 - Patients will remain on temporary PAP during the appeal process if the prior authorization is denied
 - Patients will be discontinued from temporary PAP and transitioned to unrestricted PAP if the prior authorization denial is not overturned and the program criteria is met
- Eligibility period is three months, a renewal application will be sent 30 days prior to eligibility end date



EYLEASM Retroactive Patient Assistance Program (R-PAP)

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EYLEA 4USM Retroactive Patient Assistance Program (R-PAP)

■ Current Program Design:

- To qualify for R-PAP, patients must have received EYLEATM but subsequently found a lack of coverage for EYLEA under their health plan
- Patients must meet all other PAP criteria
- R-PAP is not available when reimbursement for EYLEA is included in a DRG, APC, case rate, per-diem rate or other bundled payment

Retroactive Patient Assistance Program (R-PAP)

■ Current Program Design:

- For an insured patient to qualify for R-PAP, the provider must submit a completed SMN form, prior to administration of EYLEA (can be same day as administration)
- A patient may qualify if the following criteria are met:
 - An initial claim or prior authorization is denied and is due to a pre-existing condition or patient has exceeded an annual/lifetime benefit cap
 - Documentation of the remaining balance on patient's annual/lifetime benefit when the cost of treatment will exceed that benefit cap
 - The original claim or prior authorization is denied
 - If an appeal has not been initiated, EYLEA 4USM may assist providers in the appeal process
- The SMN must be submitted to EYLEA 4U prior to administration of EYLEA
 - Patient and provider signatures will be included
 - Patient will be pre-qualified for the PAP
- Income documentation will be required in the event the claim and the appeal are denied
- For fully qualified R-PAP patients, providers will receive a shipment of product to replace the provider-owned stock used for that patient





EYLEA™ Wastage/Breakage Returns Program

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Overview – Scope of Program

■ Objective:

- The overall objective of the EYLEA 4USM Wastage and Breakage Returns Program (RP) will be to provide replacement EYLEA to providers if the product was damaged or unused, in accordance with Regeneron's Returns Goods Policy

■ Program Goals:

- The primary goals of the EYLEA 4U RP will be to:
 - Assist in the drug replacement process between the provider and Regeneron
 - Facilitate the scheduling of replacement drug orders

■ Assistance:

- Processing of RP requests from providers
- Coordination of RP order requests with Besse Medical



Eligibility

■ Current Eligibility Criteria:

- Product has not been administered, billed or reimbursed
- Product unusable due to patient being misdiagnosed (after vial drawn)
- Patient refused product (after vial drawn)
- Product dropped or mishandled
- Product not properly refrigerated or stored

EYLEA 4USM Wastage and Breakage Drug Returns Program

■ Current Program Design:

- Providers will contact the program via phone to request the necessary RP form
- Providers will complete and fax form to the program
- Program representatives will enter the data from the form into the program database
- Wastage and breakage requests will be sent via email to Regeneron (Bob Davis) for determination
 - REGN contacts the provider's office
 - REGN provides mailing instructions and postage to the office
 - REGN contacts Besse to issue replacement of the vial
- Determination letter will be faxed to the site upon determination
- Providers are limited to up to 2 replacement vials per year

Additional Information

- The returns program will be tracked within the program database and within Regeneron to ensure sites are not taking advantage of the program
- Correspondence for the EYLEA 4USM Wastage and Breakage Drug Replacement Program is as follows:
 - RP enrollment form: can be faxed to the provider
 - Missing information: follow up will be completed via phone by program representatives
 - Determination letter: provider will receive notification via fax stating if they are eligible for the return
 - EYLEA 4U Wastage and Breakage Returns Program address is as follows:
 - EYLEA 4U Reimbursement Support Program
PO Box 220578
Charlotte, NC 28222-0578





Underinsured Government Patient Assistance

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Underinsured Government Patient Assistance

- Government Copay Foundation Program
- Terms of Agreement reviewed and approved by legal
- Copay foundation analysis was conducted and the following recommendations were made:*
- Provide funding to 2 national foundations (PANF & CDF)
- Total 12 month donation equates to \$800,000
 - CDF: Payment of \$125,000 paid quarterly
 - PANF: Payment of \$75,000 paid quarterly
 - Quarterly payments made to foundations
 - Follow-up each quarter with the foundations to ensure donation is meeting the needs of EYLEA patients
 - Proposed payment schedule is as follows: September 15, December 15...
- Please refer to copay analysis for additional information on PANF and CDF





EYLEA 4USM

Commercial Copay Program

REGENERON

Overview – Scope of Program

■ Objective:

- Support privately-insured patients with EYLEA™ by assisting with their out-of-pocket medication cost.

■ Program Goals:

- Ensure appropriate access based on patient eligibility criteria
- Distribute Copay Cards along with Welcome Letters explaining how to use the program
- Adjudicate medical and pharmacy claims to facilitate assistance with out of pocket costs
- Coordination of copay reimbursement for eligible expenses

■ Key Services:

- Coordination with EYLEA 4U™ Reimbursement Services Program
- Customer Service Support
- Phone-Based Eligibility Determination
- Copay Card Activation
- Claims Adjudication and Payment Processing
 - The copay card is not a "debit" card
 - Pharmacy transactions are electronic and can be run through the primary insurance - get a real time response and be subsequently filed through the copay program electronically and paid.
 - Physician office claims - there will be a delay in reimbursement. The claim will have to be submitted to the primary payor, wait to receive the determination from the primary payor, and then submit to the copay program where it will be reviewed and a manual check will be issued to the patient based upon the program criteria.
- Regeneron Copay Bank Account Set Up
- Payment Thresholds and Check Administration

Am I eligible? How do I enroll?

■ Current Eligibility Criteria:

- Patient must have private/commercial insurance
- Must reside in the United States, Puerto Rico, Guam, US Virgin Islands, American Samoa, the Northern Mariana Islands
 - Excluding the state of Massachusetts.
- Patient cannot be covered by any state or federally funded programs
- Must be taking EYLEA for an approved FDA indication
- Household income must be less than \$100,000 (household size is irrelevant)

■ How do I enroll?

- Please call 1-855-Copay77 (855-267-2977)
- Copay Specialists will ask the eligibility questions above and validate eligibility
- The Patient will be required to provide a copy of the latest Federal Tax Return (FTR), a current W2 or a copy of the last two pay stubs to validate household income
 - Information will be sent via fax to (888) 379-8801.
- Once the income is verified the Copay Specialists will complete the patient's enrollment in the EYLEA 4U Copay Program



EYLEA 4USM Copay Program

■ Current Program Design:

- Upon receipt of the income documentation and completed eligibility screening, the Copay Specialist will determine if the patient is eligible for the program
 - Once approved, the patient will be enrolled in the program for 12 months
 - Copay ID Card, Welcome Letter, and Proof of Expenditure Form will be mailed to the patient
 - The Copay Program will conduct a “Welcome Call” to the referring/treating provider and explain the program benefits, eligibility period and provide information on how to submit requests for reimbursement
 - Patient is responsible for the first \$5.00 of expenses related to drug costs for EYLEATM
 - The program covers 100% of the drug co-pay amount over \$5 (which is the patient’s responsibility).
- The Program will reimburse the remaining out-of-pocket expenses that are directly related to the purchase of EYLEA for the remainder of the patient’s 12 months of eligibility

How are expenses reimbursed?

■ Specialty Pharmacy (If applicable):

- Patient will provide the pharmacy with a copy of their copay card
- Pharmacy will run the charges through the patient's primary payor and then run the balance through the copay program (applying program benefits)
- Transactions are electronic and occur real-time. This minimizes the patient's interaction and potential out of pocket delay

■ Physician/Outpatient Facility/Home Care Agencies:

- Physician, Outpatient Facility or Home Care Agencies - purchase and/or administer EYLEA™
- Once services are rendered they will submit a claim to the patient's primary payor
- Once the primary payor provides their benefit determination, the provider will assist the patient with their request for reimbursement to the copay program. This could include; providing the necessary documentation and submitting the documentation on their behalf, or providing the patient with the necessary documentation to request reimbursement in which the patient would submit this information directly to the copay program.
- To provide reimbursement, we require a statement showing the primary payor's consideration/payment for EYLEA. This may include any/or a combination of an Explanation of Benefits, itemized bill from the provider, payment statement, etc. Once we received the necessary information, the program will review the request for reimbursement and apply the appropriate program benefits. The program will issue a manual check to the patient for the eligible reimbursement amount.

Additional Information

- Manual checks are issued every two weeks
- Payments will be issued to the patient
- Program has a 90-day look back period. This allows the patient to submit a request for reimbursement on expenses incurred within 90 days prior to their enrollment in the copay program (but only if patient would have been eligible for the program at the time of payment)
- Correspondence for the EYLEA 4USM Copay Program is as follows:
 - Patient Welcome Letter – this is accompanied by the EYLEA 4U Copay Card and a Proof of Expenditure Form. This provides an overview of the program and details around how to submit a request for reimbursement.
 - Missing Information Letters – Patient and/or Provider – this is used when we have received a request for reimbursement with insufficient supporting documentation to complete the review. We make multiple attempts by phone prior to mailing the letter.
 - Patient Final Letter – This will generate to the patient 6-weeks (45 days) prior to the patient's end of eligibility date. This reminds the patient that their currently eligibility period will be ending soon and provides information regarding how to re-enroll in the program if they continue to need assistance and remain eligible.
 - EYLEA 4U Copay Program Address is as follows:
 - EYLEA 4U Copay Program
 - P.O. Box 220566
 - Charlotte, NC 28222-0566

